



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0086]

Agency Information Collection Activities; Proposed Collection; Comment Request; Potential Tobacco Product Violations Reporting Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in FDA's Tobacco Product Violations Reporting Form.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-N-0086 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Potential Tobacco Product Violations Reporting Form." Received comments will be placed in

the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Potential Tobacco Product Violations Reporting Form--

OMB Control Number 0910-0716--Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act amended section 201 et seq. of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321 et seq.) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. FDA is requesting an extension of OMB approval for the collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

FDA created a Tobacco Call Center (with a toll-free number: 1-877-CTP-1373). Callers are able to report potential violations of the Tobacco Control Act, and FDA may conduct followup investigations based on information received. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation occurred; product type (e.g., cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco); tobacco brand; potential violation type; type of potentially violative promotional materials; who potentially violated; and the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator's Web site (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Report), and seeks renewal of Form

FDA 3779. This form is posted on FDA's Web site. The public and interested stakeholders are also able to report information regarding possible violations of the Tobacco Control Act through the following methods: Calling the Tobacco Call Center using the Center for Tobacco Products' (CTP) toll-free number; using a fillable Form FDA 3779 found on FDA's Web site; downloading a PDF version of the form to send via email or mail to FDA; requesting a copy of Form FDA 3779 by contacting CTP and sending by mail to FDA; and sending a letter to FDA's CTP.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

| Activity and FDA Form 3779 | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Reporting violations of the FD&C Act, as amended by the Tobacco Control Act via telephone, Internet form, mail, smartphone application, or email. | 750 | 2 | 1,500 | 0.25 (15 minutes) | 375 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that submitting the information (by telephone, Internet form, paper form by mail, or email) will take 0.25 hour (i.e., 15 minutes) per response. Based on the type and rate of reporting that has been submitted through the Potential Tobacco Violation Reporting Form in the past, in addition to the increase that FDA has recently experienced in the rate of reporting due to the recent rule, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act," FDA estimates the number of annual respondents to this collection of information will be 750, who will each submit 2 reports by telephone, Internet form, paper form, or email. Each report is expected to take 0.25 hour to complete and submit; therefore, total burden hours for this

collection of information is estimated to be 375 hours (1,500 responses x 0.25 hour per response).

Dated: October 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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